

Application No. 10/583,157
February 24, 2010

AMENDMENTS TO THE CLAIMS:

OK TO ENTER: /CMW/

03/01/2010

Claim 1. (Currently Amended) A pharmaceutical composition for parenteral administration which comprises an active pharmaceutical ingredient and a non-detergent sulfobetaine (NDSB)

wherein the NDSB is a quaternary ammonium salt having a nitrogen atom and four groups R1, R2, R3, and R4 – SO₃ bound to the nitrogen atom, wherein R1, R2 and R3 can be the same and/or different and are selected from the group consisting of one or more of methyl, ethyl, propyl, butyl, pentyl, hexyl and derivatives thereof, and R4 is (CH₂)_n, wherein n is from 1 to 6, and

wherein the pharmaceutical composition is suitable for parenteral administration.

Claim 2. (Original) The pharmaceutical composition according to claim 1, wherein the active pharmaceutical ingredient is selected from the group consisting of a therapeutically effective synthetic or natural organic molecule and a therapeutically effective protein.

Claim 3. (Original) The pharmaceutical composition according to claim 2, wherein the therapeutically effective protein is selected from the group consisting of granulocyte-colony stimulating factor, interferons, interleukins, granulocyte-macrophage colony-stimulating factor, macrophage colony-stimulating factor, epidermal growth factor, erythropoietin, follicle-stimulating hormone, human serum albumin, deoxyribonuclease, fibroblast calcitonin, hematoprotein; plasminogenic activators and their precursors, cytokines; TNF family of ligands, soluble receptors, growth hormones, lipoproteins; alpha-1-antitrypsin; insulin, proinsulin, subunit A of insulin, subunit B of insulin; glucagons; blood coagulation factors, bombasine; thrombin; enkephalinase; macrophage inflammatory protein (MIP-1-alpha); relaxin A subunit, relaxin B subunit, prorelaxin; inhibin; activin; vascular endothelial growth factor; hormone receptors or growth factor receptors; integrins; protein A, protein D; rheumatoid factors; bone-derived neurotrophic factor, neurotrophin-3, -4, -5, or 6; nerve growth factor, platelet-derived growth factor, fibroblast growth factor, transformed growth factor, insulin-like growth factor, thrombopoietin, bone morphogenetic protein and superoxide dismutase.

Claim 4. (Original) The pharmaceutical composition according to claim 3, wherein the therapeutically effective protein is G-CSF.

Claim 5. (Cancelled)

Claim 6. (Currently Amended) The pharmaceutical composition according to claim [[5]]
1, wherein the NDSB is selected from the group consisting of dimethylethyl-(3-sulphopropyl)-
ammonium salt, 3-(1-pyridino)-1-propanesulfonate, dimethylbenzylammonium
propanesulfonate, dimethyl-t-butyl-(3-sulphopropyl)ammonium salt, 3-(1-methylpiperidine)-1-
propanesulfonate and dimethyl-(2-hydroxyethyl)-(sulphopropyl)-ammonium salt.

Claim 7. (Original) The pharmaceutical composition according to claim 6, wherein the
NDSB is dimethyl-t-butyl-(3-sulphopropyl)ammonium salt.

Claim 8. (Previously Presented) The pharmaceutical composition according to claim 1
wherein said composition optionally further comprises a polyol.

Claim 9. (Original) The pharmaceutical composition according to claim 8, wherein the
polyol is selected from the group consisting of sorbitol, glycerol, inositol, trehalose and
mannitol.

Claim 10. (Previously Presented) The pharmaceutical composition according claim 1,
wherein said composition optionally further comprises one or more pharmaceutically acceptable
excipients.

Claim 11. (Original) The pharmaceutical composition according to claim 10, wherein a
pharmaceutically acceptable excipient is selected from the group consisting of EDTA and
DMSO.

Claim 12. (Currently amended) A process for preparation of a pharmaceutical
composition, wherein the pharmaceutical composition of claim 1 is prepared by mixing a NDSB
with therapeutically effective amount of an active pharmaceutical ingredient.

Claims 13 – 16. (Cancelled)